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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/963,878 | 09/26/2001 | Bruce S. Ellingboe | CV-0290US | 9174 |

7590 10/06/2003

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/06/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,878

Applicant(s)

ELLINGBOE ET AL.

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) 13-101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species A, claims 1-12 in Paper No. 8 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9-12 rejected under 35 U.S.C. 102(b) as being anticipated by US 5,462,416 to Dennehey et al. Dennehey discloses a blood pumping cassette within a blood circuit with a plurality of tubing lines (134, 136) that connect to fluid passageways within the cassette. The cassette is comprised of a rigid portion connected to a flexible portion. (See FIG 9; column 6.) The blood circuit further comprises a control unit with a component interface region and an area that interfaces with the cartridge, and a pump. (See FIG 76; column 20.) The system further comprises blood reservoirs (see column 16, lines 40-45), flow control clamps, air bubble detectors (see column 10, lines 25-35). The cassette further comprises pressure sensors and valve stations that are actuated to regulate fluid flow (see columns 6-7).

With regard to applicant's claim limitations drawn to the functions of the blood circuit, the pump, the reservoir, flow control clamp, sensors in the claims, the claims

Art Unit: 3762

recite the functions of the devices in narrative form, and such recitations have not been given patentable weight. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,540 to Abbott et al in view of US 5,462,416 to Dennehey et al. Abbot discloses a blood circuit with a cassette that serves to control fluid flow in a cardioplegia

circuit. Use of the cassette serves to simplify the fluid control, preventing the operator from having to manually set up the fluid channels in the complicated circuit. Abbot discloses that the system incorporates an oxygenator 14, pumps in the pump cassette that send fluid from the oxygenator through the rest of the circuit back to the patient, and a cardioplegia circuit that combines blood and cardioplegia solution in the circuit (see columns 3-4). Abbot fails to disclose the tubing lines, valves, and sensors as claimed, but Dennehey, as delineated above, disclosed those claimed limitations. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add the tubing lines, valves, and sensors, along with the other claimed limitations found in the Dennehey device, to the cassette disclosed by Abbott in order to provide a simplified, controllable cardioplegia fluid circuit, as taught by Abbot.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,540 to Abbott et al in view of US 5,462,416 to Dennehey et al, in view of US 5,820,579 to Plotkin. Abbot and Dennehey disclose the blood circuit and cassette as claimed including an air detector, but fails to disclose a valve with diverting mechanism. It is well known within the art of blood processing to provide air detectors and divert blood with bubbles in it so as not to introduce air bubbles into the patient, as taught by Plotkin. Plotkin discloses a cardiopulmonary bypass circuit with a pump and an oxygenator and an air detector 36. When the air detector senses a bubble in the line, microprocessor/controller 50 employs valve 38 to divert the blood and air bubble into recycle line 48, which serves as a reservoir, in order to prevent the air bubble from being introduced to the patient. Plotkin discloses that his system is better than

Art Unit: 3762

conventional air trap systems, since the diverting technique diverts a minimum amount of fluid while maintaining adequate blood output to the patient (see column 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a diverting mechanism to the cassette and air sensor of the Dennehey/Abbot device in order to prevent introduction of air to the patient while maintaining adequate blood flow in the system.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 4,756,705 Beijbom et al
 - i. Heart-lung system with cassette
- b. US 5,899,873 Jones et al
 - ii. Cardioplegia system with cassette

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0873.

Lrd 
26 September 2003



ANGELA D. SYKES
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